

HOFLAND et al.
Appl. No. 10/591,847
Atty. Ref.: 620-454
Amendment
February 20, 2009

AMENDMENTS TO THE DRAWINGS

Please insert the attached three (3) Replacement Sheets of drawings (Figures 1A, 1B, 1C, 1D, 2A and 2B) in place of the two (2) sheets of drawings filed September 5, 2006.

REMARKS

Reconsideration is requested.

Claims 1-10 are pending.

Page 1 of the Office Action states that the drawings have been objected to however the Office Action contains no further details of any basis for objecting to the drawings. The originally-filed drawings have been replaced with the attached drawings, which include labels of an increased size as compared to the originally-filed drawings. No new matter has been added. A separate marked-up copy, or Annotated Sheets, of the drawings is not believed to be required as it was only the clarity of the originally-filed drawing sheets which has been revised. The Examiner is requested to contact the undersigned, preferably by telephone, in the event anything further is required with regard to the drawings.

Claim 5 has been revised, without prejudice, based on, for example, the disclosure at page 5, lines 15-17 of the specification. No new matter has been added.

Reconsideration and withdrawal of the obviousness-type double patenting rejection of claim 5 over claim 12 of U.S. Patent No. 6,265,385 as the kit of claim 12 of the cited patent would not have made obvious the invention of specific separate forms required by claim 5. The Examiner is urged to application that the obviousness-type double patenting rejection relates to the description of claim 12 of the cited patent, as opposed to the teaching of the art in general, as suggested by the Examiner's comments on page 3 of the Office Action dated August 20, 2008. Withdrawal of the obviousness-type double patenting rejection of claim 5 is requested.

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The Section 102 rejection of claim 5 over WO97/25044 is obviated by the above amendments. Specifically, the cited application, which is understood to be the same substantive disclosure of the above-cited U.S. Patent No. 6,265,385, fails to specifically teach or describe the components required of claim 5. Withdrawal of the Section 102 rejection is requested.

The Section 103 rejection of claims 1-4 and 6-10 over WO97/25044 (Jensen) in view of Palepu (U.S. Patent No. 4,963,551) is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

The present application demonstrates that the triple combination of a topoisomerase-II poison and a bis-dioxypiperazine and radiation therapy causes a surprising extension in the survival of test animals when compared to the use of the topoisomerase-II poison with either of radiation therapy or bis-dioxypiperazine alone.

The rejection is understood to be based on the single comment in Palepu et al that "Other highly desirable properties of ADR-529 are activity as a ... sensitizer to ionising radiation ..." from column 1, lines 33-35 of Palepu et al. The applicants submit however that this purportedly beneficial activity, which is listed alongside other allegedly beneficial activities, is neither tested nor verified in Palepu et al. In fact, there is no further mention anywhere in Palepu et al of this alleged activity. The applicants believe that an unsupported statement such as that found in the cited art would not have led one to believe with any predictability that the presently claimed invention could be successfully made.

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It is noted, furthermore, that labeling a compound as a sensitizer to ionising radiation does not mean that a synergism in results obtained will be demonstrated when using that compound with radiation when compared to the use of the compound and radiation alone.

In fact, the present application states on page 15, lines 26-27, that dexrazoxane, which is also known as ICRF-187 or ADR-529, does not affect survival in test animals when used in combination with radiotherapy alone. This is also demonstrated in Fig 2B of the present application. Thus, whether or not ADR-529 is considered to be a sensitizer to ionizing radiation, when used in combination with radiotherapy alone it does not demonstrate better results than when used without radiotherapy.

Given these findings, the applicants believe that the ordinarily skilled person would not have considered that the triple combination of a topoisomerase-II poison and a bis-dioxypiperazine and radiation therapy would provide the superior results demonstrated by the present application.

Withdrawal of the Section 103 rejection is requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned, preferably by telephone, in the event anything further is required.

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Respectfully submitted,

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